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March 4, 2021

VIA ECF

The Honorable Leda Dunn Wettre
United States Magistrate Judge
Martin Luther King, Jr. Federal Building
and United States Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Fresenius Kabi USA, LLC v. Par Sterile Products, LLC et al.*
Civil Action No. 16-4544 (SDW) (LDW)

Dear Judge Wettre:

Defendants Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc. (collectively, “Par”) submit this letter pursuant to the Court’s February 18, 2021 Order that “the parties shall file letters on or before March 4, 2021 setting forth their views of next steps to be taken in this litigation and a proposed schedule to complete the same.” Dkt. 250.

The Third Circuit did *not* hold that the District Court reached the wrong outcome when it granted summary judgment for Par.¹ Rather, the Third Circuit’s Opinion provided instructions to guide the District Court’s evaluation of the parties’ existing summary judgment briefing on remand. In so doing, the Third Circuit expressly contemplated that the District Court may reach the same outcome—granting summary judgment for Par—on the basis of the present record.²

Par respectfully submits that additional briefing on Par’s motion for summary judgment is neither necessary, warranted, nor contemplated by the Third Circuit’s Opinion. The parties’ prior briefing and evidentiary submissions establishing undisputed material facts are more than sufficient to permit the District Court to conduct the analysis prescribed by the Third Circuit.

¹ See generally Opinion, *Fresenius Kabi, LLC v. Par Sterile Prods., LLC*, No. 20-1618 (3d Cir. Feb. 11, 2021), Dkt. 61 [hereinafter “Op.” or “Opinion”].

² See, e.g., Op. at 9 n.9 (noting that “other deficiencies in the record” may “absolve” the District Court of engaging in *Wellbutrin* patent-law analysis); *id.* at 10 n.12 (instructing that, “[o]n remand, the District Court may choose to consider whether the exclusivity agreement even constitutes anticompetitive conduct because if it does not, then no patent analysis is needed”); *id.* at 10–11 n.12 (noting that “[v]arious facts [in the record] shed light on the issue of substantial foreclosure,” and providing guidance on relevant record facts); *id.* at 10 (remanding to allow the “the District Court to examine the record to determine whether a reasonable jury could find that Par’s patents would have blocked Fresenius Kabi’s market entry”).

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The Third Circuit emphasized that “no patent analysis is needed” if the District Court determines that Par’s conduct did not *substantially foreclose competition* or that Fresenius did not incur cognizable *antitrust injury*.³ As the Third Circuit observed, for instance, “Fresenius Kabi was offered the chance to compete for an exclusive arrangement with BCN for its API via a competitive monetary offer but declined to pursue it,” and “there were other API suppliers who were willing to provide API to Fresenius.”⁴ The parties have already briefed these arguments at length,⁵ and made factual submissions totaling thousands of pages.⁶ There is no need for more briefing; Par’s arguments are ripe for consideration, and the District Court should grant summary judgment for Par on the basis of the current record.

With respect to *causation*—the lack of which formed the basis for the District Court’s prior summary judgment order—the Third Circuit instructed that the District Court should “consider the substance of” [the] patent claims” implicated by Fresenius’s theory of causation, consistent with the *Wellbutrin* decision,⁷ but only if the District Court determines that “the record permits the District Court to engage in such an analysis.”⁸ If, for example, there are “grounds to reject [Fresenius’s patent experts’] opinions,” or if there are “ambiguities in what [Fresenius’s] proposed ANDA would have contained,” or if there are “other deficiencies in the record,” the District Court may grant summary judgment in Par’s favor without a full-scale patent-law analysis.⁹

If summary judgment in Par’s favor is warranted based on one or both of the other grounds discussed above, there is no need for the District Court to address causation. But if the District Court chooses to consider causation—and if it determines that “the record permits [it] to engage in such an analysis”¹⁰—it can perform the analysis on the basis of prior briefing and factual submissions. The parties’ summary judgment briefs fully address Fresenius’s causation theories, including Fresenius’s patent-law arguments and related expert opinions.¹¹ And that briefing shows that Par’s patents, even under a *Wellbutrin* patent-law analysis, cut off the chain

³ See Op. at 10 n.12.

⁴ Op. at 10 n.12 (citing *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 79, 84 (3d Cir. 2010)).

⁵ See Par’s Mot. for Summ. J. at 17–37 (Dkt. 154); Fresenius’s Opp’n to Par’s Mot for Summ. J. at 20–39 (Dkt. 180); Par’s Reply in Support of Mot. for Summ. J. at 3–17 (Dkt. 199).

⁶ By Par’s count, the parties submitted over 18,000 pages’ worth of exhibits in support of their summary judgment briefing.

⁷ Op. at 9 (quoting *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 167 (3d Cir. 2017)).

⁸ See Op. at 9–10 (“Whether the record permits the District Court to engage in such an analysis of course will be for it to decide.”).

⁹ Op. at 9 nn.8–9.

¹⁰ Op. at 9–10.

¹¹ See Par’s Mot. for Summ. J. at 37–48 (Dkt. 154); Fresenius’s Opp’n to Par’s Mot for Summ. J. at 39–49 (Dkt. 180); Par’s Reply in Support of Mot. for Summ. J. at 17–23 (Dkt. 199).

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of causation, barring Fresenius's claims. For that independent reason, summary judgment should again be granted in Par's favor.

For these reasons, Par respectfully submits that the most efficient and expeditious path forward would be for the District Court to decide Par's motion for summary judgment on the basis of the parties' prior briefing and factual submissions, and with the benefit of the Third Circuit's guidance. More briefing and evidence would serve only to compound the burden and expense borne by the District Court and the parties and to further forestall the resolution of this nearly-five-year-old litigation.

To the extent the District Court believes it would benefit from further argument, Par will gladly make itself available for a hearing at the Court's convenience.

Respectfully yours,

McELROY, DEUTSCH, MULVANEY & CARPENTER, LLP

A handwritten signature in blue ink, reading "George C. Jones", is centered on the page. The signature is written in a cursive, flowing style.

GEORGE C. JONES

cc: All counsel (via ECF and e-mail)